FOOD STANDARDS AGENCY NORTHERN IRELAND CONSULTATION
Title: EU Regulation 609/2013 on Foods for Specific Groups
CONSULTATION SUMMARY PAGE

Date consultation launched: 12 February 2016
Closing date for responses: 11 March 2016

Who will this consultation be of most interest to?
Manufacturers of food for specific nutritional purposes, dietitians, enforcement officers. We understand there to be very few manufacturers of such products in Northern Ireland, however if you are aware of any not included on the circulation list below, please forward their details to us or pass the consultation information on to them, so we can more accurately calculate the impact of this regulation and to ensure all appropriate views are obtained.

What is the subject of this consultation?
The Food Standards Agency in Northern Ireland is seeking views on an enforcement regime to be introduced via domestic legislation in the form of a Statutory Rule (SR), so that EU Regulation 609/2013 on foods for specific groups can be enforced by district councils in Northern Ireland. The intended effect of the SR will be to consolidate existing domestic laws into a single SR, thus simplifying the legal framework making the legislation easier to enforce and removing unnecessary rules and burdens on business.

We are asking for stakeholders' views on the appropriateness of the proposed approach to enforcement, which is based for the most part on Improvement Notices and, where an immediate risk to public health is involved, criminal sanctions.

The benefit of Improvement Notices will be to give district councils greater flexibility in their enforcement of the rules and will reduce the amount of prosecutions in Northern Ireland.

This is a limited technical consultation; the list of consultees is at Annex B. The informal consultation will start 12 February 2016 and end 11 March 2016. Responses should be submitted to executive.support@foodstandards.gsi.gov.uk by 17.00 on 11 March 2016.

What is the purpose of this consultation?
To inform interested parties that Regulation (EU) No. 609/2013 on foods for specific groups was adopted to simplify existing rules covering foods for particular nutritional uses (Directive 2009/39/EC referred to as PARNUTS) and seek opinions on how this should be enforced within Northern Ireland.

If you would prefer to receive future FSA consultations by e-mail, or if you no longer wish to receive information on this subject please notify the named person in this consultation.
Responses to this consultation should be sent to:

Name: James O’Neill
Division/Branch: Executive Support Unit
FOOD STANDARDS AGENCY IN NORTHERN IRELAND
Tel: 028 90 417733
Fax: 028 90 417726

Postal address:
10A-10C Clarendon Road
BELFAST
BT1 3BG
Email: executive.support@foodstandards.gsi.gov.uk

Is an Impact Assessment included with this consultation?

<table>
<thead>
<tr>
<th>Yes</th>
<th>X</th>
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<tr>
<td>No</td>
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</table>
Background to the Regulation

Regulation (EU) No. 609/2013 on foods for specific groups was adopted to simplify existing rules covering foods for particular nutritional uses (Directive 2009/39/EC referred to as PARNUTS). The foods for specific groups Regulation provides for the adoption of four Delegated Regulations to establish detailed rules on the composition, labelling and advertising for each of the four specific food categories:

- infant and follow-on formula
- processed cereal-based food and baby food
- medical foods (foods necessary for the dietary management of particular medical conditions)
- total diet replacement for use in energy restricted diets for weight reduction

It has been necessary to revise the PARNUTS framework legislation to take account of food manufacturing and scientific developments, and the adoption of new pieces of legislation. Of particular importance in this context are the legislation on fortified food, nutrition and health claims, and food information for the consumer. Foods previously regulated under the PARNUTS framework, such as meal replacements for weight control will be treated as general foods and regulated under existing EU legislation on food labelling and nutrition and health claims.

Domestic legislation is required to deal with consequential matters arising from the coming into force of the foods for specific groups Regulation, which applies from 20 July 2016. The Statutory Rule (SR) will make the foods for specific groups Regulation workable and enforceable in Northern Ireland. The Delegated Regulations on infant and follow-on formula and medical foods came into force on 26 January 2016. The Delegated Regulations on processed cereal-based food and baby food and total diet replacement for use in energy restricted diets for weight reduction are further behind in their adoption and the SR will be amended at later date to include these provisions.

The SR will revoke a number of regulations, thus simplifying the legal framework. The use of Improvement Notices to achieve compliance will be considered in this consultation and these will make reference to the Delegated Regulations covering the main technical requirements of the foods for specific groups Regulation.

The foods for specific groups Regulation applies to all Member States from 20 July 2016. There are transitional periods for complete compliance with the new compositional and labelling requirements of three years for medical foods, four years for medical foods for infants and four years for infant and follow-on formula (except those manufactured from protein hydrolysates which will have a five year transition period). The individual Delegated Regulations will specify the relevant timescales.

The intended effect of the new regulatory proposal will be to consolidate existing domestic laws into a single SR, thus simplifying the legal framework making the legislation easier to enforce and removing unnecessary rules and burdens on businesses.
Focus of Consultation: Enforcement

We are consulting on a proposed change to the current enforcement regime. Currently, if a food business operator (FBO) is found guilty of an offence then the FBO is liable to a fine of up to £5,000, a criminal sanction. Our proposal is that the first formal action under the foods for specific groups Regulation would be to issue an Improvement Notice rather than a criminal sanction in some cases.

• WHAT THE PROPOSED CHANGE WILL MEAN FOR ENFORCEMENT

The proposed change from frontline criminal offences to Improvement Notices backed up with a criminal offence for a failure to comply with an Improvement Notice effectively decriminalises regulatory offences in appropriate cases.

• HOW IMPROVEMENT NOTICES WILL WORK

Improvement Notices are already in use in other areas of food labelling (e.g. the Food Information (Northern Ireland) Regulations 2014), so they are already understood by the industry and by environmental health officers and appear to be working well. It is a more flexible approach giving industry additional time and support to resolve the problem identified in the Improvement Notice, enabling them to comply before it is escalated to a criminal offence.

A breach in the foods for specific groups Regulation may mainly relate to an offence in either:

a) the compositional requirements or

b) the labelling requirements for foods for specific groups and to a lesser extent other requirements such as notification, presentation, promotion and advertising.

The approach to enforcement is risk based, as outlined in Figure 1. For the most part it is envisaged that informal enforcement provisions will be used in the first instance (e.g. verbal and written warnings) to ensure that labelling is compliant. If the authorised officer has reason to believe that an informal approach will not result in a successful outcome then a more formal approach should be considered and an Improvement Notice may be issued. However, where there is an immediate risk to public health (e.g. compositional requirements for infant formulae) the authorised officer should work with the business to ensure the food is promptly removed from the market under the powers of the Food Safety (Northern Ireland) Order 1991 and consideration given to whether prosecution is appropriate. Once the risk to vulnerable consumers is minimised, then informal enforcement provisions will be used to ensure the food is compliant.

Following the risk-based principles means that it is likely that the majority of breaches will result in informal enforcement action, which may escalate to issuing an Improvement Notice. One exception relates to our international commitment to the Code of Practice for the Marketing of Breast-milk Substitutes and the Department of Health’s policy to encourage exclusive breastfeeding for around the first six months of life because of the health benefits to mothers and babies. In this case we would want recourse to criminal sanctions for policy reasons.
BENEFITS OF THE PROPOSAL

This new enforcement regime for foods for specific groups effectively decriminalises the majority of offences under the current enforcement regime for PARNUTS where the first formal offence is criminal sanctions. The benefit of Improvement Notices will be to give district councils greater flexibility in their enforcement of the rules and will reduce the amount of prosecutions. In practice it may be helpful to identify which breaches remain as criminal offences under the proposed enforcement regime and which will be decriminalised. The provisions are detailed in two of the four Delegated Regulations (infant and follow-on formulae and medical foods) enclosed in the consultation package but the Delegated Regulations on processed cereal-based food and baby food and total diet replacements are not yet available for consultation. The criminal sanctions relate to compositional and advertising/promotional requirements for infant formulae, highlighted in Figure 2 and to compositional requirements for foods for special medical purposes, highlighted in Figure 3.

APPEALS PROCESS

The intention is to introduce a process for appeals. An Improvement Notice, once served, may be appealed to the Magistrates Court if the business doesn’t agree with the conditions of the Notice. The appeals process to be put in place will be in line with Improvement Notices used for the Food Information (Northern Ireland) Regulations 2014 under the Food Safety Order (Northern Ireland) 1991.

The primary objective of any enforcement action must be to achieve compliance in the most effective way and as set out in the Food Law Practice Guidance (https://www.food.gov.uk/sites/default/files/multimedia/pdfs/ni-coppg1012.pdf).

Foods for specific groups Improvement Notices should be used in line with the district councils’ enforcement policy and must be considered as part of the escalation of enforcement action in line with the hierarchy of enforcement.

COSTS OF THE REGULATORY PROPOSAL

Introduction of the new SR would result in minimal familiarisation costs for industry and for enforcement (see Regulatory Impact Assessment enclosed in the consultation package for information). There would be a marginal ongoing reduction in the burden on new businesses entering the market as a result of consolidating the current eight SRs into one SR. Familiarisation costs are limited as these are more concerned with the EU foods for specific groups Regulation and much less so with the SR. In addition, Improvement Notices are already in use in other areas of food labelling (e.g. the Food Information (Northern Ireland) Regulations 2014), so they are already understood by the industry and by environmental health officers.
Explanatory Figures

Figure 1

Foods for specific groups Regulation enforcement flow chart

- **Branch in FSG (Northern Island) Regulations 2016 disseminated**

- **Relates to a composition offense**

- **Relates to a risk that a vulnerable group will suffer serious harm to health**

- **What are the circumstances of the breach?**

- **Use of informal enforcement provisions to ensure that composition or labelling is complaint. May include verbal and written warnings**

- **Enforcement authorities to work with business to ensure food promptly is removed from the market – consider prosecution under the Food Safety (Northern Ireland) Order 1991**

- **Once risk to vulnerable consumers minimised, use of informal enforcement provisions to ensure that composition or labelling is complaint. May include verbal and written warnings**

- **Front line enforcement action – IMPROVEMENT NOTICE issued**

- **In serious cases where the business has failed to respond satisfactorily to the use of enforcement mechanisms, front line enforcement action – CRIMINAL OFFENCE**

- **Failure to comply with the Improvement Notice – CRIMINAL OFFENCE**

- **Not exceeding Level 5 on the standard scale, which is currently £5,000**

- **No**
### Offences relating to the infant formula and follow-on formula Delegated Regulation

<table>
<thead>
<tr>
<th>Provision of the Infant Formula and Follow-on Formula Delegated Regulation</th>
<th>Provisions to be read with the provision of the Infant Formula and Follow-on Formula Delegated Regulation</th>
<th>Remains a criminal offence?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Article 1(2) (prohibition on marketing products other than infant formula as suitable for certain purposes)</td>
<td></td>
<td>Yes</td>
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</tbody>
</table>
| Article 2(1) (compositional requirements for infant formula) | Articles 1(1) and 2(3) and Annexes I and III  
Article 4(1) of the EU Regulation | Yes |
| Article 2(2) (compositional requirements for follow-on formula) | Articles 1(1) and 2(3) and Annexes II and III  
Article 4(1) of the EU Regulation | Yes |
| Article 3(1) (suitability of ingredients for infant formula) | Articles 1(1) and 3(3) and paragraph 2 of Annex I  
Article 4(1) of the EU Regulation | Yes |
| Article 3(2) (suitability of ingredients for follow-on formula) | Articles 1(1) and 3(3) and paragraph 2 of Annex II  
Article 4(1) of the EU Regulation | No |
| Article 4(2) (requirements relating to residue levels) | Articles 1(1) and 4(1), (3) and (5) and Annex IV  
Article 4(1) of the EU Regulation | No |
| Article 4(4) (prohibition on the use of plant protection products) | Articles 1(1) and 4(1) and (5) and Annex V  
Article 4(1) of the EU Regulation | No |
| Article 5(1) (requirements as to the name of infant formula and follow-on formula not manufactured entirely from cow’s milk or goat’s milk proteins) | Article 1(1) and Part A of Annex VI  
Article 4(1) of the EU Regulation | No |
<table>
<thead>
<tr>
<th>Article (section)</th>
<th>Relevant Articles/Annexes</th>
<th>No/Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Article 5(2) (requirements as to the name of infant formula and follow-on formula manufactured entirely from cow's milk or goat's milk proteins)</td>
<td>Article 1(1) and Part B of Annex VI, Article 4(1) of the EU Regulation</td>
<td>No</td>
</tr>
<tr>
<td>Article 6(2) (additional mandatory particulars for infant formula)</td>
<td>Articles 1(1) and 6(4) and (5)</td>
<td>No</td>
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<tr>
<td></td>
<td>Article 13(2) and (3) of FIC, Article 4(1) of the EU Regulation</td>
<td></td>
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<tr>
<td>Article 6(3) (additional mandatory particulars for follow-on formula)</td>
<td>Articles 1(1) and 6(4) and (5)</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Article 13(2) and (3) of FIC, Article 4(1) of the EU Regulation</td>
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<tr>
<td>Article 6(5) (language requirements)</td>
<td></td>
<td>No</td>
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<tr>
<td>Article 6(6) (requirements as to the labelling, presentation and advertising of infant formula and follow-on formula)</td>
<td>Article 1(1), Article 4(1) of the EU Regulation</td>
<td>No</td>
</tr>
<tr>
<td>Article 7(1) (additional information in the mandatory nutrition declaration in respect of mineral and vitamins) except the third paragraph</td>
<td>Annexes I and II, Article 4(1) of the EU Regulation</td>
<td>No</td>
</tr>
<tr>
<td>Article 7(3) (prohibition on repeating the information in the mandatory nutrition declaration on labelling)</td>
<td>Article 1(1), Article 30(3) of FIC, Article 4(1) of the EU Regulation</td>
<td>No</td>
</tr>
<tr>
<td>Article 7(5) (requirements relating to the calculation, expression and presentation of energy values)</td>
<td>Articles 1(1) and 7(6), (7) and (8) and Annex VII, Articles 30(1) to (5), 31(1), (3), 34(1) to (4) and the first paragraph of (4), 32, 33(1) to (4), 34(1) to (4) and the first paragraph of (5), and 35(1) of and Annexes XIII, XIV and XV to FIC, Article 4(1) of the EU Regulation</td>
<td>No</td>
</tr>
<tr>
<td>Article 8 (prohibition on nutrition and health claims on infant formula)</td>
<td>Article 1(1), Article 4(1) of the EU Regulation</td>
<td>No</td>
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<tr>
<td>Article 9 (statements related to lactose and DHA)</td>
<td>Article 1(1)</td>
<td>No</td>
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<tr>
<td>Article 4(1) of the EU Regulation</td>
<td></td>
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<tr>
<td>Article 10 (requirements for promotional and commercial practices for infant formula)</td>
<td>Yes</td>
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<tr>
<td>Article 12(1) (notifying the competent authority about placing infant formula on the market)</td>
<td>No</td>
<td></td>
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<tr>
<td>Article 12(2) (notifying the competent authority about placing follow-on formula on the market)</td>
<td>No</td>
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</table>

**Figure 3**

**Offences relating to the Food for special medical purposes Delegated Regulation**

<table>
<thead>
<tr>
<th>Provision of the Food for Special Medical Purposes Delegated Regulation</th>
<th>Provisions to be read with the provision of the Food for Special Medical Purposes Delegated Regulation</th>
<th>Remains a criminal offence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Article 2(2) (suitability of formulation)</td>
<td>Article 1</td>
<td>No</td>
</tr>
<tr>
<td>Article 4(1) of the EU Regulation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Article 2(3), first paragraph (compositional requirements for food developed for infants)</td>
<td>Articles 1 and 2(4) and Part A of Annex I</td>
<td>Yes</td>
</tr>
<tr>
<td>Article 4(1) of the EU Regulation</td>
<td></td>
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</tr>
<tr>
<td>Article 2(3), second paragraph (compositional requirements for food developed for people other than infants)</td>
<td>Articles 1 and 2(4) and Part B of Annex I</td>
<td>Yes</td>
</tr>
<tr>
<td>Article 4(1) of the EU Regulation</td>
<td></td>
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<tr>
<td>Article 3(2) (requirements relating to residue levels)</td>
<td>Articles 1 and 3(1), (3) and (5) and Annex II</td>
<td>No</td>
</tr>
<tr>
<td>Article 4(1) of the EU Regulation</td>
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<tr>
<td>Article 3(4) (prohibition on the use of plant protection products)</td>
<td>Articles 1 and 3(1) and (5) and Annex III</td>
<td>No</td>
</tr>
<tr>
<td>Article 4(1) of the EU Regulation</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Article 4 (requirements as to naming food) | Article 1 and Annex IV  
| Article 4(1) of the EU Regulation | No |
| Article 5(2) (additional mandatory particulars) | Article 1  
| Article 13(2) and (3) of FIC  
| Article 4(1) of the EU Regulation | No |
| Article 6(1) (additional information for the mandatory nutrition declaration) | Article 1 and Annex I  
| Article 4(1) of the EU Regulation | No |
| Article 6(2) (prohibition on repeating the information in the mandatory nutrition declaration on labelling) | Article 1  
| Article 30(3) of FIC  
| Article 4(1) of the EU Regulation | No |
| Article 6(4) (requirements relating to the calculation, expression and presentation of energy values) | Articles 1 and 6(5), (6) and (7)  
| Articles 30(1) to (5), 31(1), (3) and the first paragraph of (4), 32, 33(1) to (4), 34(1) to (4) and the first paragraph of (5), and 35(1) of and Annexes XIII, XIV and XV to FIC  
| Article 4(1) of the EU Regulation | No |
| Article 7 (prohibition on nutrition and health claims) | Article 1  
| Article 4(1) of the EU Regulation | No |
| Article 8(1) (language requirements for food for special medical purposes intended for infants) | No |
| Article 8(2) (labelling, presentation and advertising restrictions for food intended for infants) | No |
| Article 8(3) (requirement to distinguish food for special medical purposes intended for infants from infant formula and follow-on formula) | No |
| Article 8(4) (restrictions on advertising food for special medical purposes intended for infants), first paragraph | Article 8(4), third paragraph | No |
| Article 8(5) (restrictions on point-of-sale advertising, giving samples of, and otherwise promoting food for special medical purposes intended for infants) | No |
| Article 8(6) (prohibition on promotional gifts), so far as it relates to free, low-priced products, samples or any other promotional gifts of food for special medical purposes intended for infants | No |
| Article 9 (notifying the competent authority about placing food for special medical purposes on the market) | No |
Consultation Questions

Question 1

Is it helpful to specify in the SR particularly important requirements that would attract criminal sanction if they are breached, or should all requirements potentially attract a criminal sanction if breached so that an authorised officer can make a judgement in each case as to the appropriate enforcement action?

If the former, provision in the SR might look like the following:

**Offences and penalties**

1. A person is guilty of an offence if they fail to comply with any of the following provisions as read with Article 4(1) (prohibition on placing non-conforming food on the market)—

   (a) in relation to infant formula and follow-on formula, Article 9(1) and 9(3) of the Regulation (general compositional requirements) and the provisions of the infant formula and follow-on formula Delegated Regulation, Article 1(2), Article 2(1), Article 2(2), Article 3(1) and Article 10; or

   (b) Article 2(3) of the provisions of the food for special medical purposes Delegated Regulation

   (c) Article 9(2) of the Regulation (substances in dangerous quantities).

2. A person guilty of an offence under this regulation is liable on summary conviction to a fine.

Question 2

If only breaches of particularly important requirements are to attract criminal sanction, have the right requirements been identified in Figures 2, 3 and 4?

Question 3

Do you agree with the proposals for a more proportionate enforcement regime, namely Improvement Notices with the back-stop non-custodial criminal offence which exists for a failure to comply (See Article 9(2) Food Safety Order (Northern Ireland) 1991)
Thank you on behalf of the Food Standards Agency in Northern Ireland for participating in this public consultation.

Yours faithfully

James O’Neill
Executive Support Unit
FSA in Northern Ireland

Enclosed

Annex A: Standard Consultation Information
Annex B: List of interested parties
Annex C: Impact Assessment (attached separately)
Annex D: Draft Statutory Rule (attached separately)
Queries
1. If you have any queries relating to this consultation please contact the person named on page 1, who will be able to respond to your questions.

Publication of personal data and confidentiality of responses
2. In accordance with the FSA principle of openness our Information Centre at Aviation House will hold a copy of the completed consultation. Responses will be open to public access upon request. The FSA will also publish a summary of responses, which may include personal data, such as your full name and contact address details. If you do not want this information to be released, please complete and return the Publication of Personal Data form, which is on the website at http://www.food.gov.uk/multimedia/worddocs/dataprotection.doc Return of this form does not mean that we will treat your response to the consultation as confidential, just your personal data.

3. In accordance with the provisions of Freedom of Information Act 2000/Environmental Information Regulations 2004, all information contained in your response may be subject to publication or disclosure. If you consider that some of the information provided in your response should not be disclosed, you should indicate the information concerned, request that it is not disclosed and explain what harm you consider would result from disclosure. The final decision on whether the information should be withheld rests with the FSA. However, we will take into account your views when making this decision.

4. Any automatic confidentiality disclaimer generated by your IT system will not be considered as such a request unless you specifically include a request, with an explanation, in the main text of your response.

Further information
5. A list of interested parties to whom this letter is being sent appears in Annex C. Please feel free to pass this document to any other interested parties, or send us their full contact details and we will arrange for a copy to be sent to them direct.

6. Please let us know if you need paper copies of the consultation documents or of anything specified under ‘Other relevant documents’.

7. This consultation has been prepared in accordance with HM Government Code of Practice on Consultation, available at: http://www.berr.gov.uk/files/file47158.pdf The Consultation Criteria from that Code should be included in each consultation and they are listed below:

The Seven Consultation Criteria

Criterion 1 — When to consult
*Formal consultation should take place at a stage when there is scope to influence the policy outcome.*

Criterion 2 — Duration of consultation exercises
*Consultations should normally last for at least 12 weeks with consideration given to longer timescales where feasible and sensible.*
Criterion 4 — Accessibility of consultation exercises
Consultation exercises should be designed to be accessible to, and clearly targeted at, those people the exercise is intended to reach.

Criterion 5 - The burden of consultation
Keeping the burden of consultation to a minimum is essential if consultations are to be effective and if consultees’ buy-in to the process is to be obtained.

Criterion 6 - Responsiveness of consultation exercises
Consultation responses should be analysed carefully and clear feedback should be provided to participants following the consultation.

Criterion 7 - Capacity to consult
Officials running consultations should seek guidance in how to run an effective consultation exercise and share what they have learned from the experience.

8. Criterion 2 states that Consultations should normally last for at least 12 weeks with consideration given to longer timescales where feasible and sensible.

9. The Code of Practice states that an Impact Assessment should normally be published alongside a formal consultation. We consider that the impact on both businesses and enforcement authorities of the proposed Regulations will be negligible. We have however produced a draft impact assessment for these proposals for which we would welcome your input. This draft impact assessment is attached as Annex C.

10. For details about the consultation process (not about the content of this consultation) please contact: Food Standards Agency Consultation Co-ordinator, Room 2B, Aviation House, 125 Kingsway, London, WC2B 6NH. Tel: 020 7276 8140.

Comments on the consultation process itself

11. We are interested in what you thought of this consultation and would therefore welcome your general feedback on both the consultation package and overall consultation process. If you would like to help us improve the quality of future consultations, please feel free to share your thoughts with us by using the Consultation Feedback Questionnaire at:

   http://www.food.gov.uk/multimedia/worddocs/consultfeedback.doc

12. If you would like to be included on future Food Standards Agency consultations on other topics, please advise us of those subject areas that you might be specifically interested in by using the Consultation Feedback Questionnaire at:

   http://www.food.gov.uk/multimedia/worddocs/consultfeedback.doc

The questionnaire can also be used to update us about your existing contact details.
Annex B

List of consultees
Northern Ireland District Council Environmental Health Officers
Northern Ireland Food Liaison Group
Southern Trust in Northern Ireland
South Eastern Health and Social Care Trust
Northern Health and Social Care Trust in Northern Ireland
Ulster University
Queen’s University Belfast
Northern Ireland Health and Social Care Board – Medicines Management Team
Northern Ireland Food Advisory Committee
The New You Plan Total Food Replacement
Title: The Foods for Specific Groups Regulations (Northern Ireland) 2016
IA No: FSA

Lead department or agency: FSA in NI
Other departments or agencies: FSA in Scotland, Welsh Assembly Government and DH England

Impact Assessment (IA)
Date: 08/09/15
Stage: Consultation
Source of intervention: EU
Type of measure: Secondary legislation
Contact for enquiries: Annie Chambers 028 9041 7708 / James O'Neill 028 9041 7733

Summary: Intervention and Options

<table>
<thead>
<tr>
<th>Cost of Preferred (or more likely) Option</th>
<th>Total Net Present Value £m</th>
<th>Business Net Present Value £m</th>
<th>Net cost to business per year (EANCB on 2009 prices) £m</th>
<th>In scope of One-In, One-Out?</th>
<th>Measure qualifies as OUT</th>
</tr>
</thead>
</table>

What is the problem under consideration? Why is government intervention necessary?
Domestic legislation is required to deal with consequential matters arising from the coming into force of Regulation (EU) no. 609/2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control in Northern Ireland. While the Foods for Specific Groups (FSG) Regulation has direct effect in all Member States, the offences and penalties for breaching FSG will be contained in national legislation.

The main groups that are likely to be affected are manufacturers of products where the FSG legislation has changed in relation to the current legislation. The main food sectors affected include infant formula, follow-on formula and growing up milks, baby foods, medical foods, slimming foods, very low calorie diet foods (VLCDs), gluten-free foods, and sports foods and drinks.

A new Statutory Rule (SR) would make the FSG Regulation workable and enforceable in Northern Ireland, it would revoke a number of regulations, simplifying the legal framework. Improvement notices to achieve compliance will be considered as the preferred option in this impact assessment, and these will make reference to the Delegated Regulations covering the main technical requirements of FSG.

What are the policy objectives and the intended effects?
The intended effect of the new regulatory proposal will be to consolidate existing domestic laws into a single SR, thus simplifying the legal framework making the legislation easier to enforce and removing unnecessary rules and burdens on businesses.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)
1. Do nothing - Regulation (EU) no. 609/2013 on foods for specific groups (FSGs) will not be enforced
2. Self-regulation - A full revocation of the legislation to make way for industry self-regulation
3. SR with current enforcement provisions - Failure to comply will constitute a criminal offence with fines for the food business operator (FBO)
4. SR with new enforcement provisions - Introduce Improvement Notices as the first formal action under the FSG Regulation.

Option 1: Do nothing - the FSG Regulation will still come into force, but we would not have the domestic legislation to make it workable and enforceable in Northern Ireland. The UK would be in breach of its legal obligations under the EU Treaty and may face infraction procedures. Option 1 is therefore disregarded.

Option 2: Industry self-regulation, we believe it will be necessary for Government to continue to legislate, as with most other food labelling measures, to ensure a level playing field for all producers and to avoid misleading consumers

Option 3: An SR with current enforcement provisions. Enforcement action is only pursued where informal action has been unsuccessful and the current enforcement action takes the form of a criminal prosecution in relation to the contravention.

Option 4: An SR with Improvement Notices. Change the current enforcement regime with no additional cost on businesses so that the first formal action under the FSG Regulation would be to issue an Improvement Notice and a criminal prosecution would proceed only if the Improvement Notice was not complied with.

Option 4 is the preferred approach.

Will the policy be reviewed? No. If applicable, set review date: Not applicable in Northern Ireland

Does implementation go beyond minimum EU requirements? No
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.

<table>
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<th>Small</th>
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<td></td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
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</table>

What is the CO₂ equivalent change in greenhouse gas emissions?
(Million tonnes CO₂ equivalent)

<table>
<thead>
<tr>
<th></th>
<th>Traded:</th>
<th>Non-traded:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible SELECT SIGNATORY: ____________________________ Date: _______________________
Summary: Analysis & Evidence

Policy Option 1

Description: Do nothing - Regulation (EU) no. 609/2013 on foods for specific groups (FSGs) will not be enforced

FULL ECONOMIC ASSESSMENT

<table>
<thead>
<tr>
<th>Price Base Year</th>
<th>PV Base Year</th>
<th>Time Period Years</th>
<th>Net Benefit (Present Value (PV)) (£m)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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<td>Low:</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>COSTS (£m)</th>
<th>Total Transition (Constant Price)</th>
<th>Average Annual (excl. Transition) (Constant Price)</th>
<th>Total Cost (Present Value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
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<tr>
<td>High</td>
<td></td>
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</tr>
<tr>
<td>Best Estimate</td>
<td>&lt;£0.01m</td>
<td>£0.00m</td>
<td>&lt;£0.01m</td>
</tr>
</tbody>
</table>

Description and scale of key monetised costs by ‘main affected groups’

Option 1 - As an EU Regulation, the FSG Regulation is binding in its entirety and directly applicable in all Member States. It is therefore not necessary to transpose the provisions of the FSG Regulation into domestic law. Doing nothing would mean that the FSG Regulation will still come into force, but we would not have the domestic legislation to make it workable and enforceable in Northern Ireland. National legislation must be in place across the four UK administrations by 20 July 2016, if not the UK would be in breach of its legal obligations under the EU Treaty and may face infraction procedures.

Option 1 is therefore disregarded as an option, but it is the baseline against which other options are appraised.

Other key non-monetised costs by ‘main affected groups’

None identified

<table>
<thead>
<tr>
<th>BENEFITS (£m)</th>
<th>Total Transition (Constant Price)</th>
<th>Average Annual (excl. Transition) (Constant Price)</th>
<th>Total Benefit (Present Value)</th>
</tr>
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<tbody>
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<tr>
<td>Best Estimate</td>
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<td>£0.0m</td>
</tr>
</tbody>
</table>

Description and scale of key monetised benefits by ‘main affected groups’

The benefits arising are not easily quantifiable, however, there would be cost to government if infraction procedures where faced.

Other key non-monetised benefits by ‘main affected groups’

N/A

Key assumptions/sensitivities/risks – taking this option would result in EU Infraction Procedures against the UK.

Discount rate (%)

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:

<table>
<thead>
<tr>
<th>Costs: £0.00m</th>
<th>Benefits: £0.00m</th>
<th>Net: £0.00m</th>
<th>In scope of OIOO?</th>
<th>Measure qualifies as</th>
</tr>
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<tbody>
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<td>N/A</td>
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</tr>
</tbody>
</table>
Summary: Analysis & Evidence

Policy Option 2

Description: Allow for self-regulation of the enforcement of Regulation (EU) no. 609/2013 in Northern by industry.

FULL ECONOMIC ASSESSMENT

<table>
<thead>
<tr>
<th>Price Base Year</th>
<th>PV Base Year</th>
<th>Time Period Years</th>
<th>Net Benefit (Present Value (PV)) (£m)</th>
</tr>
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<tbody>
<tr>
<td></td>
<td></td>
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<td></td>
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<td></td>
<td>Best Estimate: &lt;£0.01m</td>
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</table>

<table>
<thead>
<tr>
<th>COSTS (£m)</th>
<th>Total Transition (Constant Price) Years</th>
<th>Average Annual (excl. Transition) (Constant Price)</th>
<th>Total Cost (Present Value)</th>
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<tbody>
<tr>
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<tr>
<td>High</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Best Estimate</td>
<td>&lt;£0.01m</td>
<td></td>
<td>&lt;£0.01m</td>
</tr>
</tbody>
</table>

Description and scale of key monetised costs by ‘main affected groups’

Option 2: Government/Administrations across the four UK regions are the only bodies able to revoke, replace or amend the current legislation. Whilst we have looked at the option of a full revocation of the legislation to make way for industry self-regulation, we believe it remains necessary for Government to continue to legislate, as with most other food labelling measures, to ensure a level playing field for all producers and to avoid misleading consumers.

This option has been discounted as Industry self-regulation for FSGs would lead to an inconsistent approach with other food labelling areas, as well as the same risk of EU Infraction Procedures being instigated as in option 1. Informal consultation with industry indicates a preference for regulation in this area due to the potential risk of a “free-for-all” market.

Other key non-monetised costs by ‘main affected groups’

None identified

<table>
<thead>
<tr>
<th>BENEFITS (£m)</th>
<th>Total Transition (Constant Price) Years</th>
<th>Average Annual (excl. Transition) (Constant Price)</th>
<th>Total Benefit (Present Value)</th>
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<td>High</td>
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</tr>
<tr>
<td>Best Estimate</td>
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<td>£0.0m</td>
<td>£0.0m</td>
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</tbody>
</table>

Description and scale of key monetised benefits by ‘main affected groups’

The benefits arising are not easily quantifiable and are detailed under non-monetised benefits.

Other key non-monetised benefits by ‘main affected groups’

Reduced legal/court costs and less time in court.

Key assumptions/sensitivities/risks

Discount rate (%)

BUSINESS ASSESSMENT (Option 2)

<table>
<thead>
<tr>
<th>Direct impact on business (Equivalent Annual) £m:</th>
<th>In scope of OIOO?</th>
<th>Measure qualifies as</th>
</tr>
</thead>
<tbody>
<tr>
<td>Costs: £0.00m</td>
<td>Benefits: £0.00m</td>
<td>Net: £0.00m</td>
</tr>
</tbody>
</table>
Summary: Analysis & Evidence

Policy Option 3

Description: Allow for the enforcement of Regulation (EU) no. 609/2013 in Northern by introducing a new SR with enforcement provisions, in the form of criminal prosecution in relation to contravention.

FULL ECONOMIC ASSESSMENT

<table>
<thead>
<tr>
<th>Price Base Year</th>
<th>PV Base Year</th>
<th>Time Period Years</th>
<th>Net Benefit (Present Value (PV)) (£m)</th>
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<tbody>
<tr>
<td></td>
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<td>Low: High: Best Estimate: &lt;£0.01m</td>
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</table>

**COSTS (£m)**

<table>
<thead>
<tr>
<th></th>
<th>Total Transition (Constant Price) Years</th>
<th>Average Annual (excl. Transition) (Constant Price)</th>
<th>Total Cost (Present Value)</th>
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<td>High</td>
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</tr>
<tr>
<td>Best Estimate</td>
<td>&lt;£0.01m</td>
<td>£0.00m</td>
<td>&lt;£0.01m</td>
</tr>
</tbody>
</table>

**Description and scale of key monetised costs by ‘main affected groups’**

**Option 3:** An SR retaining current enforcement provisions, would essentially maintain the status quo regarding the enforcement of European regulation in this area, i.e. impose no additional costs on business. This would mean that enforcement of the FSG Regulation would be done on a risk-based approach. Where there is not a significant risk to human health, enforcement officers’ work with businesses in their area, to ensure food labelling complies with legal requirements, through inspection visits based on risk assessment. Currently enforcement action is pursued where informal action has been unsuccessful and takes the form of a criminal prosecution in relation to the contravention. Under this, where an FBO is found guilty of an offence then the FBO is liable to a fine (not exceeding Level 5 on the standard scale, which is currently £5,000).

This option has been discounted as other food labelling legislation now uses enforcement notices, which is the preferred, less time and money intensive option. Retaining criminal prosecution is restrictive on businesses.

Introduction of the new SR would result in some familiarisation costs. (which need to be quantified). There would be a marginal ongoing reduction in the burden on new businesses entering the market as a result of consolidating the current 8 SRs into one.

**Other key non-monetised costs by ‘main affected groups’**

None identified

**BENEFITS (£m)**

<table>
<thead>
<tr>
<th></th>
<th>Total Transition (Constant Price) Years</th>
<th>Average Annual (excl. Transition) (Constant Price)</th>
<th>Total Benefit (Present Value)</th>
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<tr>
<td>High</td>
<td>Optional</td>
<td>Optional</td>
<td>Optional</td>
</tr>
<tr>
<td>Best Estimate</td>
<td>£0.00m</td>
<td>£0.00m</td>
<td>£0.00m</td>
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</table>

**Description and scale of key monetised benefits by ‘main affected groups’**

The benefits arising are not easily quantifiable and are detailed under non-monetised benefits.

**Other key non-monetised benefits by ‘main affected groups’**

Key assumptions/sensitivities/risks

Discount rate (%)

**BUSINESS ASSESSMENT (Option 3)**

Direct impact on business (Equivalent Annual) £m:

Costs: £0.00m  Benefits: £0.00m  Net: £0.00m

In scope of OIOO?  Measure qualifies as

N/A  N/A
Summary: Analysis & Evidence

Description: Allow for the enforcement of Regulation (EU) no. 609/2013 in Northern by introducing a new SR with enforcement provisions, which introduce Improvement Notices as the first formal action under the FSG regulation.

FULL ECONOMIC ASSESSMENT

<table>
<thead>
<tr>
<th>Price Base Year</th>
<th>PV Base Year</th>
<th>Time Period Years</th>
<th>Net Benefit (Present Value (PV)) (£m)</th>
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COSTS (£m)

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<th>High</th>
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<td></td>
<td>&lt;£0.01m</td>
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</table>

Description and scale of key monetised costs by ‘main affected groups’

Option 4 - Preferred option - would change the current enforcement regime in a manner that results in no additional costs to businesses. Currently, if an FBO is found guilty of an offence then the FBO is liable to a fine (not exceeding Level 5 on the standard scale, which is currently £5,000). Under Option 4 the first formal action under the FSG Regulation would be to issue an Improvement Notice rather than a fine. This will be a saving to industry and a more flexible approach giving industry additional time and support to resolve the problem identified in the Improvement Notice, enabling them to comply before it is escalated to a criminal offence. Introduction of the new SR would result in familiarisation costs of approximately £?. There would be a marginal ongoing reduction in the burden on new businesses entering the market as a result of consolidating the current eight SRs into one.

Familiarisation costs are limited as these are more concerned with the EU FSG Regulation and much less so with the SR. In addition, Improvement Notices are already in use in other areas of food labelling (e.g. the Food Information Regulations 2014), so they are already understood by industry.

BENEFITS (£m)

<table>
<thead>
<tr>
<th>Low</th>
<th>High</th>
<th>Best Estimate</th>
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<tr>
<td></td>
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<td>£0.00m</td>
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</tbody>
</table>

Description and scale of key monetised benefits by ‘main affected groups’

The benefits arising are not easily quantifiable and are detailed under non-monetised benefits.

Other key non-monetised benefits by ‘main affected groups’

There is a potential benefit to Government in terms of moving from the current frontline criminal sanctions regime to the new Improvement Notice regime. It is anticipated that any gains would originate from reduced court costs as the number of hearings will be reduced as issues will be resolved through issuing Improvement Notices and the time saved to enforcement officers in resolving the issues more quickly instead of preparing for a court case.

Government will also benefit as Option 4 is likely to result in better monitoring of the market regarding foods for specific groups, as Improvement Notices will be recorded, whereas informal warnings from enforcement practitioners will not. The UK Government will therefore be more accountable in terms of its enforcement of European regulation in this area, providing evidence for FVO visits or where challenged by the European Commission (e.g. following a formal complaint to the Commission from a business or another Member State regarding UK enforcement in this area).

If we pursue the preferred approach, this will constitute a consolidation of European regulation resulting in a consolidation of domestic regulation into a single SR. There is no gold-plating.

Key assumptions/sensitivities/risks

Discount rate (%)

BUSINESS ASSESSMENT (Option 4)

<table>
<thead>
<tr>
<th>Direct impact on business (Equivalent Annual) (£m):</th>
<th>In scope of OIOO?</th>
<th>Measure qualifies as</th>
</tr>
</thead>
<tbody>
<tr>
<td>Costs: £0.00m</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Benefits: £0.00m</td>
<td></td>
<td></td>
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<tr>
<td>Net: £0.00m</td>
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</tbody>
</table>
Executive Summary (figures in this section need to be verified)

1. The policy issue and rationale for Government intervention

1.1. The rationale is our responsibility under the EU Treaty to enforce European legislation. Our aim is to pass domestic legislation dealing with consequential matters arising from the coming into force of Regulation (EU) no. 609/2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control in Northern Ireland.

1.2. Due to the diversification and specialisation of foods for particular uses (PARNUTS), Regulation (EU) no. 609/2013 was adopted to simplify existing rules covering these well-defined categories of food. Regulation (EU) no. 609/2013 on foods for specific groups (FSG Regulation) would be implemented via a new Statutory Rule (SR), revoking a number of SRs as a result of the FSG Regulation coming into force.

1.3. In our implementation we can simplify and update existing rules by treating foods such as gluten-free foods1 as general foods, and regulate them under existing EU legislation on food labelling and nutrition and health claims. The EU Regulation provides for the adoption of four delegated acts to establish detailed rules on the composition, labelling and advertising for each of the four specific food categories in the Regulation. Intervention is justified to reduce market distortion and consumers being misled, for example, consumers might pay more for a chocolate labelled as ‘suitable for diabetics’ compared to a similar ‘normal’ chocolate bearing a nutrition claim “low in sugar” as the former could be considered as being a specially formulated dietetic food for diabetic people.

1The FSG Regulation repeals the gluten Regulation (EU) No. 41/2009 on 20 July 2016 and from that date these foods will be regulated under the food information for the consumer Regulation no. 1169/2011 (EU FIC).

2. Policy objectives and intended effects

1.1. Our policy objective is to legislate to make the FSG Regulation workable and enforceable in Northern Ireland, with the intended effect of consolidating existing domestic laws into a single SR. The new SR will simplify the legal framework, revoking the regulations listed in Annex B.

1.2. The SR will contain enforcement provisions which will make reference to the Delegated Regulations covering the main technical requirements of FSG Regulation. Under the preferred option, this would involve the use of Improvement Notices to achieve compliance.

1.3. The intended effect of the new regulatory proposal will be to consolidate existing domestic laws into a single SR, thus simplifying the legal framework making the legislation easier to enforce and removing unnecessary rules and burdens on businesses.

3. Policy options considered, including alternatives to regulation

Option 1: Do nothing - Regulation (EU) no. 609/2013 on foods for specific groups (FSGs) will not be enforced.

Option 2: Self-regulation - A full revocation of the legislation to make way for industry self-regulation.

Option 3: SR with current enforcement provisions - Failure to comply will constitute a criminal offence with fines for the food business operator (FBO).

Option 4: SR with new enforcement provisions - Introduce Improvement Notices as the first formal action under the FSG Regulation.

Expected level of business impact

1. This IA considers the business impact of the proposed SR. The wider unavoidable impacts of EU regulation no. 609/2013 are discussed in Annex A for context.

The main groups that are likely to be affected are manufacturers of products where the FSG legislation has changed in relation to the PARNUTS legislation. The categories of foodstuffs covered by the FSG legislation is restricted to infant formula, follow-on formula, baby foods and foods for special medical purposes and total diet replacements for weight control (TDR). The FSG Regulation removes other foodstuffs regulated under the current framework, such as gluten-free foods, which will in future be regulated under other existing food law measures. The Regulation also asks the commission to produce a report on the necessity of specific rules on sports foods and milks for older children (growing up milks). This follows concerns by some member states and the European Parliament that there is currently no evidence to support the need for such products as FSGs and they can more appropriately be regulated under existing EU food law.

The main food sectors affected include slimming foods, very low calorie diet foods (VLCDs), gluten-free foods, formula milk, growing up milks and sports foods and drinks. Other sectors where little regulatory changes are proposed (infant formula, follow-on formula, baby foods and medical foods), will nevertheless need to understand the changes to the legislation, and impact should be limited to familiarisation costs.
A UK-wide industry questionnaire seeking information on the costs and benefits that may arise as a result of implementing the FSG Regulation was launched March 2015. The responses were collated and have informed the discussion in Annex A. However, the findings are limited as only the British Specialist Nutrition Association (BSNA) and the European Specialist Sports Nutrition Alliance (ESSNA) responded. That said, the BSNA represents manufacturers of FSGs with the exception of TDRs, and a detailed response on TDRs was received from the European Very Low Calorie Diet Industry group following industry consultation of the draft working documents on TDRs.

Option 2: Industry

Option 2, industry self-regulation, is strictly deregulatory and would introduce no additional direct costs to industry. However, this approach would lead to an inconsistent approach with other food labelling areas and informal consultation with industry indicates a preference for regulation in this area due to the risk of a “free-for-all” market.

Consumers

As a significant proportion of businesses in the food sector are small or medium sized enterprises (SMEs), as well as the rapid turnover of businesses in the sector, it is not thought that self-regulation would provide sufficient protection for consumers. This could therefore lead to an increase in misleading information and labelling on foods and unauthorised practices e.g. prohibited advertising of infant formulae which may encourage its use to the detriment of breast feeding; exclusive breastfeeding is encouraged for around the first six months of life because of the health benefits to mothers and babies.

Government

Self-regulation would reduce burdens for enforcement officers but would be inconsistent with the enforcement approach in other areas of food labelling.

Option 3: Industry

Option 3 would maintain the status quo regarding the enforcement of European regulation in this area, i.e. this option imposes no additional costs on business. However, currently the first formal action is a criminal offence whereby a food business operator (FBO) found guilty of an offence would be liable to a fine. This is restrictive on businesses.

There would be transition costs due to the need for businesses to familiarise themselves with the new SR. We estimate it would take a manager 2 hours to become fully familiarised with the new SR. This may be an overestimate, as much of the familiarisation required is expected to be subsumed under familiarisation with the EU legislation itself. Salary has been estimated using ASHE provisional 2014 median wage data for production managers and directors, uplifted for 30% on-costs. This results in a cost of £52.36 per business affected.

We have not as yet identified any baby food businesses in Northern Ireland, Likewise, no infant formula manufacturers have been noted in Northern Ireland.

Again, no businesses manufacturing Foods for Specific Medical Purposes (FSMPs) have been identified in Northern Ireland.

We are unaware of any manufacturers of Total Dietary Replacement products in Northern Ireland.

We would welcome feedback about any of the above that you are aware of, so their input into this impact assessment and consultation may be sought.

Consolidation of the existing 8 SRs into just one may result in a reduced administrative burden, especially for businesses newly entering into the market. However, we do not consider this saving to be substantial. The 8 SRs apply to different markets, with some covering gluten free foods, others covering baby food etc. It is therefore unlikely that managers are currently required to read all 8, rather only 2 or 3. The substantive content of the SRs will also not be reduced, so time would only be saved in terms of searching for the relevant legislation. As industry bodies currently clearly signpost the relevant legislation in a single place, it is not evident that there would be substantial time savings.

Consumers

Although the SR does not affect consumers directly, it is worth noting that the FSG Regulation maintains the high level of consumer protection as PARNUTS, ensuring adequate nutritional composition of the food to protect the most vulnerable consumers and appropriate consumer information (e.g. foods intended for infants and young children and medical foods). Removing the concept of dietetic food may impact some consumers e.g. those who found dietetic statements such as “suitable for diabetics” helpful, but our informal consultation e.g. views expressed by Diabetes UK, suggests that regulating such food under general food law is a benefit.

Government

Although this would maintain the status quo regarding the enforcement of European regulation in this area, district councils would need to become familiar with the new SR. It is estimated that it would take one enforcement officer
one hour to read and become familiar with the SR and the new enforcement regime. The hourly pay rate for enforcement officers is between £16 and £25 – averaging approximately £27 per hour once uprated to account for non-wage labour costs and overheads, taken as 30%. The total one-off cost to the 11 district councils is therefore estimated at approximately £300.

Ongoing workloads for EHOs are not expected to increase as a result of this SR, as enforcement work for the products affected is already required.

**Option 4 (preferred option)**

**Industry**

Option 4 (preferred option) would change the current enforcement regime with no additional cost on businesses. Currently, if an FBO is found guilty of an offence then the FBO is liable to a fine (not exceeding Level 5 on the standard scale, which is currently £5,000. Under Option 4 the first formal action under the FSG Regulation would be to issue an Improvement Notice rather than a fine. This will be a potential saving to industry and represents a more flexible approach giving industry additional time and support to resolve the problem identified in the Improvement Notice, enabling them to comply before it is escalated to a criminal offence.

Familiarisation costs will be similar to Option 3. These are limited as they are more concerned with the EU FSG Regulation and less so with the SR. In addition, Improvement Notices are already in use in other areas of food labelling (e.g. the Food Information Regulations (Northern Ireland) 2014), so they are already understood by industry.

**Impact on Government**

The impact on Government of Option 4 is purely the cost for familiarisation of the SR for district councils as per Option 3 above. As per Option 3, ongoing workloads for enforcement officers are not expected to increase as a result of this SR as enforcement work for the products affected is already required.

The use of Improvement Notices in the SR under Option 4 is a change from the current enforcement regime, but enforcement practitioners will be familiar with their use for other food labelling legislation (e.g. the Food Labelling Regulations (Northern Ireland) 2014) and therefore additional familiarisation costs are considered negligible.

**Consumers**

The SR does not affect consumers directly, as per Option 3 above

**Benefit to industry**

The only regulatory change to be assessed is the move to a different enforcement regime. The broad benefit to industry in moving from the current frontline criminal sanctions regime to a new regime is that enforcement will be carried out by way of an Improvement Notice, followed up by a criminal offence in cases where businesses continue to ignore the Notice. This may give FBOs a better chance to rectify issues before the matter comes before a criminal court.

Industry may benefit from reduced costs resulting from fewer prosecutions in a system where an Improvement Notice will precede any legal prosecution. In an ordinary case, criminal prosecution will result only if the business in receipt of the Improvement Notice does not comply with the Notice either from the outset or if, following an unsuccessful appeal against the Notice to a magistrate’s court; they continue to fail to comply with the Notice.

**Benefit to Government**

There is a potential benefit to Government in terms of moving from the current frontline criminal sanctions regime to the new Improvement Notice regime. It is anticipated that any gains would originate from reduced court costs as the number of hearings will be reduced as issues will be resolved through issuing Improvement Notices, and the time saved to enforcement officers in resolving the issues more quickly instead of preparing for a court case.

Government will also benefit as Option 4 is likely to result in better monitoring of the market regarding foods for specific groups as Improvement Notices will be recorded whereas informal warnings from enforcement practitioners will not. The UK Government will therefore be more accountable in terms of its enforcement of European regulation in this area, providing evidence for FVO visits or where challenged by the European Commission (e.g. following a formal complaint to the Commission from a business or another Member State regarding UK enforcement in this area).
Table 9: Summary of total monetised costs and benefits of option 4

<table>
<thead>
<tr>
<th></th>
<th>Year 0</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
<th>Year 5</th>
<th>Year 6</th>
<th>Year 7</th>
<th>Year 8</th>
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<th>Annual Cost or Benefit</th>
<th>Equivalent Annual Cost or Benefit</th>
<th>Present Value</th>
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<tbody>
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Discussion of Impact of Regulation (EU) no. 609/2013 on foods for specific groups

The main requirements of the regulation will be found in four Delegated Acts (DA) which are yet to be laid. Possible cost implications identified from current drafts of the four Commission Delegated Regulations are provided below:

(i) Compositional and information requirements for infant formula and follow-on formula and information requirements relating to infant and young child feeding

- Protein hydrolysates – A new requirement that the safety and suitability of each specific formulae containing protein hydrolysates has to be established by clinical evaluation (submission of dossiers) by European Food Safety Authority (EFSA) will impose a cost on business, including the notification requirement being extended to follow-on-formulae for such products. As these will no longer be infant formula and follow-on formula medical foods there is a cost implication as medical foods are generally more expensive (i.e. a loss of a of income for industry but a possible benefit for consumers or Government/NHS prescriptions).
- Lactose-free (LF) – currently LF infant formula and follow-on formula products are marketed as Foods for Special Medical Purposes (FSMP). The new DA will prevent them from being marketed as FSMP which are generally priced above regular infant formula and follow-on formula, resulting in loss of income for industry but a possible benefit for consumers or Government/NHS prescriptions.
- Compositional changes due to new and revised micronutrient requirements / minimums / maximums will impose costs on businesses required to reformulate products.
- Innovation – The EFSA approval process for new products containing protein hydrolysates may limit new products coming to market
- Font size - small 200ml ready to feed (RTF) cartons may not have enough space on the largest surface area for point 0.9mm, as required under the DA. Some products may therefore require substantial repackaging to achieve compliance.
- Mandatory Dietary Health Advice (DHA) – there may be formulae on the market which currently do not contain DHA – these would face reformulation costs.
- Article 6, 2. ‘Mandatory particulars’ – under 2006/141/EC the mandatory labelling statement is worded ‘to the effect that the product is suitable. The new labelling requirements contain extra information which will be mandatory. This raises another potential for font size issues among smaller products, and the potential for substantial repackaging requirements.
- Article 12 2. ‘Notification’, requires follow on formula to be notified when ‘other substances’ are used which are not listed in the Annex. This is unclear as to what constitutes an ‘other substance’, and notification is an additional cost for follow-on formula in this instance.
- The Delegated Regulation should apply four years after its entry into force (20 July 2016, will apply July 2020) and should apply five years after entry into force for infant formula and follow-on formula manufactured from protein hydrolysates developed to satisfy the nutritional requirements of infants (will apply July 2021).

(ii) Compositional and information requirements for processed cereal-based food and baby food

- Article 1, Processed-cereal based food and baby food may only be placed on the market if they comply with this Regulation. However, Directive 2009/39/EC (Article 2,2 (b)) states - ‘However, in accordance with provisions to be adopted by the Commission, it shall be possible for foodstuffs for normal consumption which are suitable for a particular nutritional use to indicate such suitability.’ This statement has not been carried over to 609/2013 or the draft DA for weaning foods. Currently only baby foods which comply with the labelling and compositional requirements are covered, other foods which are also suitable but which may also be suitable for older children are outside scope. This ‘type’ of loophole exists because in practice any food can in theory be used for weaning. Therefore, from a cost point, a great number of products will not be able to meet the requirements in future.
- The mandatory nutrition declaration will be required to comply with EU FIC minimum font size irrespective of package size (0.9mm). There may be small product packaging which may not be able to meet this requirement such as small fruit puree pouches.
- The Delegated Regulation should apply three years after its entry into force (20 July 2016, will apply July 2019).

(iii) Compositional and information requirements for food for special medical purposes (FSMPs)
Nutrition and health claims would be forbidden on medical foods, requiring relabelling and potentially reducing sales.

Advertising restrictions which currently apply to infant formula would be extended to all medical foods for infants.

Pesticide rules to be extended to medical foods for infants – depending on current manufacturing practice this may incur additional cost.

Font size – as for processed cereal based food and baby food – some medical foods may not have enough space on the label given that a number of small scale specialist products are multi-lingual.

Article 8, 2. ‘Shall not include pictures of infants, or other pictures or text which may idealise the use of the product.’ A number of medical foods contain pictures which industry may argue ‘encourage’ children to take medical foods which are not very palatable – so there is the potential for further repackaging.

The Delegated Regulation should apply three years after its entry into force (20 July 2016, will apply July 2019) and should apply four years after entry into force for FMSPs developed to satisfy the nutritional requirements of infants (will apply July 2020).

Relabelling / Repackaging

In response to the March 2015 consultation, The European Specialist Sports Nutrition Alliance (ESSNA) stated “For companies whose products will be affected by the legislative changes a cost of around €150 per label has been estimated, mainly to cover artwork and redesign, with the cost increasing or decreasing based on the range and types of products each affected company has.”.

The British Specialist Nutrition Association’s (BSNA) response noted that “In 2010, Campden BRI published a report on behalf of Defra on research findings into the costs of labelling changes on the UK food and drinks industry which concluded that the cost of product label changes varied widely, from £1,800-£6,500 per stock keeping unit (SKU). We note this report was conducted in 2010 and has not since been updated; however we envisage the costs are only likely to have increased.”.

Both of these responses indicate a relatively low cost per product affected. We expect this cost to be further reduced in practice due to the substantial transition time built into the Delegated Acts – with the earliest applying from July 2019. It is likely that much of this relabelling could be worked into manufacturers existing timelines to refresh product lines.

BSNA reported that there are currently 530 SKUs for FSMPs in the UK market. In addition to this, they estimate there to be upwards of 800 products relating to Infants and Young Children. 2014 Kantar data identifies 126 ‘ambient slimming products’. It is therefore likely that the overarching markets captured by these delegated acts contain approximately 1,500 products.

Reformulation

BSNA note that “Product reformulation is a complex process. What may appear to be a simple flavour or ingredient change requires significant time and resource in terms of the product development process, including research to identify the ingredients to be used, recipe development and sensory testing to determine the optimum changes required. This is followed by stability trials, shelf life testing and analytical testing for quality and safety which incur further time, resources and costs. A very broad estimate for the cost of a ‘simple change’ would be £20,000 - £50,000 per product.
It is also likely that reformulation of existing products would require repetition of acceptability trials or additional clinical trials. The cost of such trials is likely to be in the range of £40,000 to £80,000 per product.”.

Where products are required to reformulate, there is therefore scope for substantial additional costs to be imposed on business. As previously discussed, it is not possible to assess how many products will be required to reformulate, nor the extent to which they will be required to do so.
List of SRs to be revoked

The following Statutory Rules will be revoked (in line with the repealing of European Regulations and Directives¹ as a result of Regulation (EU) No. 609/2013 coming into force):


The Food Safety (Information and Compositional Requirements) Regulations (Northern Ireland) 2016

Made - - - - 2016

Coming into operation - 20 July 2016

The Department of Health, Social Services and Public Safety(a) makes the following Regulations in exercise of the powers conferred by Articles 15(1), 16(1) and (2), 25, 26(3) and 47(2) of the Food Safety (Northern Ireland) Order 1991(b) and paragraph 1A of Schedule 2 to the European Communities Act 1972 (c).

These Regulations make provision for a purpose mentioned in section 2(2) of the European Communities Act 1972 and it appears to the Department of Health, Social Services and Public Safety that it is expedient for that it is expedient for the references in these Regulations to an Annex of the EU instruments listed in Regulation 2(3) to be construed as references to those instruments as amended from time to time.

In accordance with Article 47(3A) of the Food Safety (Northern Ireland) Order 1991, the Department of Health, Social Services and public safety has had regard to relevant advice given by the Food Standards Agency.

As required by Article 9 of Regulation (EU) No 178/2002(d) of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety there has been open and transparent public consultation during the preparation and evaluation of the these Regulations.

Citation and commencement

1. These Regulations may be cited as the Food Safety (Information and Compositional Requirements) Regulations (Northern Ireland) 2016 and come into operation on 20 July 2016.

Interpretation

(a) Formerly the Department of Health and Social Services; see S.I. 1999/283 (N.I.1) Article 3(6)
(b) S.I. 1991/762 (N.I.7) as amended by S.I. 1996/1663 (N.I.12), paragraphs 26 to 42 of Schedule 5 and Schedule 6 to the Food Standards Act 1999 c.28 and S.R.2004 Nos.482 and 505
(c) 1972 c.68. as amended by the Legislative and Regulatory Reform Act 2006 (c.51) and the European Union (Amendment) Act 2008(c.7). Paragraph 1A of Schedule 2 was inserted by section 28 of the Legislative and Regulatory Reform Act 2006 (2006 c.51) and amended by Part 1 of the Schedule to the European Union (Amendment) Act 2008 (2008 c.7)
2.—(1) In these Regulations:

“the Delegated Regulations” means the Infant Formula and Follow-on Formula Delegated Regulation and the Food for Special Medical Purposes Delegated Regulation;


“the Infant Formula and Follow-on Formula Delegated Regulation” means Commission Delegated Regulation (EU) 2016/127 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow on formula and as regards requirements on information relating to infant and young child feeding(b);

“the Food for Special Medical Purposes Delegated Regulation” means Commission Delegated Regulation (EU) 2016/128 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for food for special medical purposes(c);

“the Order” means the Food Safety (Northern Ireland) Order 1991;

“relevant food” means food falling into a category established by Article 1(1) of the EU Regulation.

(2) Any reference to an Article or Annex is a reference to an Article of, or an Annex to the EU Regulation.

(3) Any reference to an Annex to the EU Regulation or the Delegated Regulations is a reference to an Annex to the EU Regulation or Delegated Regulations as amended from time to time.

(4) The Interpretation Act (Northern Ireland) 1954(d) applies to these Regulations as it applies to an Act of the Assembly.

Enforcement

3. It is the duty of each district council within its district to enforce these Regulations.

Offences and penalties

4.—(1) It is an offence for a person to fail to comply with—

(a) Article 9(1) (requirement for relevant food to satisfy nutritional requirements as it applies to infant formula and follow-on formula);

(b) Article 9(2) (substances in dangerous quantities).

(c) Article 9(3) (requirements relating to substances added to relevant food) as it applies to infant formula and follow-on formula;

(d) Article 1(2), 2(1), 2(2), 3(1) or 10 of the Infant Formula and Follow-on Formula Delegated Regulation as read with the provisions specified in column 2 of the relevant entry of the table in Schedule 2; or

(e) Article 2(3) of the food for Special Medical Purposes Delegated Regulation.

A person guilty of an offence under paragraph (1) is liable on summary conviction to a fine not exceeding level 5 on the standard scale.

(a) OJ No.L 181, 29.6.2013 p.35
(b) OJ No. L25, 2.2.16, p.1
(c) OJ No. L25, 2.2.2016, p. 30
(d) 1954 c.33(NI)
Application of provisions of the Order

5.—(1) Articles 9(1) and (2) of the Order (improvement notices) apply, with the modification (in the case of Article 9(1) specified in Part 1 of Schedule 1, for the purposes of enabling an improvement notice to be served on a person requiring that person to comply with any of the provisions specified in that modification and making the failure to comply with an improvement notice an offence.

(2) Article 33 of the Order (powers of entry) applies, with the modifications (in the case of Article 33(1)) specified in Part 1 of Schedule 1, for the purposes of enabling an authorised officer—
   (a) to exercise a power of entry to ascertain whether there is or has been any contravention of a provision specified in Schedule 2;
   (b) to exercise a power of entry to ascertain whether there is any evidence of any contravention of such a provision; and
   (c) when exercising a power of entry under the provisions of Article 33 as applied by this paragraph, to exercise the powers in paragraph (6) and (7) relating to records.

(3) Article 37 (appeals) and Article 38 (appeals against improvement notices) of the Order apply, with the modifications specified in Part 3 of Schedule 1, for the purpose of enabling a decision to serve a notice referred to in paragraph (1) to be appealed.

(4) The provisions of the Order specified in column 1 of the table in Part 2 of Schedule 1 apply, with the modifications specified in column 2 of that Part.

(5) Paragraphs (1) to (3) are without prejudice to the application of the Order to these Regulations for purposes other than those specified in those paragraphs.

(6) In this regulation “authorised officer” has the same meaning as in Article 2(2)(a) of the Order.

Revocations

6. The regulations listed in Schedule 3 are revoked.

Amendments to Statutory Rules of

Sealed with the official seal of the Department of Health, Social Services and Public Safety on 0th Month 2015.

L.S.

Name

A senior officer of the Department of Health, Social Services and Public Safety
SCHEDULE 1 Regulation 5(1)

Application and modification of provisions of the Order

PART 1

Modification of Article 9(1), Article 33(1), Article 37 and 38 of the Order

1. For Article 9(1) of the Order (improvement notices) substitute—

“(1) If an authorised officer has reasonable grounds for believing that a person is failing to comply with a provision of the Food Safety (Information and Compositional Requirements) Regulations (Northern Ireland) 2016 specified in paragraph (1A), the authorised officer may, by a notice served on that person (in this Order referred to as an “improvement notice”)—

(a) state the officer’s grounds for believing that the person is failing to comply with the relevant provision;

(b) specify the matters which constitute the person’s failure to so comply;

(c) specify the measures which, in the officer’s opinion, the person must take in order to secure compliance; and

(d) require the person to take such those measures, or measures that are at least equivalent to them, within such period as may be specified in the notice.

(1A) Any provision of—


(b) Commission Delegated Regulation (EU) 2016/127 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow on formula and as regards requirements on information relating to infant and young child feeding; or

(c) Commission Delegated Regulation (EU) 2016/128 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for food for special medical purposes specified in the first column of any Part of the Table in Schedule 2 to the Food Safety (Information and Compositional Requirements) Regulations (Northern Ireland) 2016”

2. In Article 33(1) (powers of entry) for subparagraphs (a)-(c) substitute—

“(a) to enter any premises within the council’s district for the purpose of ascertaining whether there is or has been on the premises any contravention of a provision of—

(ii) Commission Delegated Regulation (EU) 2016/127 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow on formula and as regards requirements on information relating to infant and young child feeding; or
(iii) Commission Delegated Regulation (EU) 2016/128 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for food for special medical purposes specified in the first column of any Part of the Table in Schedule 2 to the Food Safety (Information and Compositional Requirements) Regulations (Northern Ireland) 2016; and
(b) to enter any business premises, whether within or outside of the council’s district, for the purpose of ascertaining whether there is on the premises any evidence of any contravention within that district of any such provisions.”

3. For Article 37(1) (appeals) substitute—

“(1) Any person who is aggrieved by a decision of an authorised officer to serve an improvement notice under Article 9(1) as applied and modified by regulation 5(1) of, and Part 1 of Schedule 1 to, the Food Safety (Information and Compositional Requirements) Regulations (Northern Ireland) 2016, may appeal to a court of summary jurisdiction”.

4. In Article 37(2A)(b) for “(1)(a)” substitute “(1) as applied and modified by regulation 5(1) of and Schedule 1 to the Food Safety (Information and Compositional Requirements) Regulations (Northern Ireland) 2016,”.

5. In both Article 38(1) and (2) (appeals against improvement notices), after “improvement notice” insert “under Article 9(1) as applied and modified by regulation 5(1) of, and Part 1 of Schedule 1 to the Food Safety (Information and Compositional Requirements) Regulations (Northern Ireland) 2016”.

PART 2

Application and modification of other provisions of the Order

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<th>Modifications</th>
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<td>Article 2(4) (extended meaning of “sale” etc.)</td>
<td>for “this Order” substitute “ the Food Safety (Information and Compositional Requirements) Regulations (Northern Ireland) 2016</td>
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<tr>
<td>Article 3 (application to food offered as prizes etc.</td>
<td>for “This Order” substitute “ the Food Safety (Information and Compositional Requirements) Regulations (Northern Ireland) 2016</td>
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<tr>
<td>Article 4 (presumptions that food intended for human consumption)</td>
<td>for “this Order” substitute “ the Food Safety (Information and Compositional Requirements) Regulations (Northern Ireland) 2016</td>
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<td>Article 19 (offences due to fault of another person)</td>
<td>For “any of the preceding provisions of this part” substitute “Article 9(2) as applied by regulation 5(1) of, and Schedule 1 to the Food Safety (Information and Compositional Requirements) Regulations (Northern Ireland) 2016 or regulation 4 of those regulations.</td>
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<tr>
<td>Article 20 (defence of due diligence)</td>
<td>In paragraph (1), for “any of the preceding provisions of this Part” substitute “Article 9(2)</td>
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as applied by regulation 5(1) of Part 1, Schedule 1 to, the Food Safety (Information and Compositional Requirements) Regulations (Northern Ireland) 2016” or regulation 4 of those regulations.”.

In paragraphs (2) for “Article 13 and 14” substitute “regulation 4 of the Food Safety (Information and Compositional Requirements) Regulations (Northern Ireland) 2016 or regulation 4 of those regulations.”.

Article 21

For “any of the preceding provisions of this part” substitute “Article 9(2) as applied by regulation 5(1) of, and Schedule 1 to the Food Safety (Information and Compositional Requirements) Regulations (Northern Ireland) 2016 or regulation 4 of those regulations”.

Article 29 (procurement of samples)

In paragraph (b)(ii), after “under Article 33 below”, insert “as applied by regulation 5(2) and Part 1 of Schedule 1 to the Food Safety (Information and Compositional Requirements) Regulations (Northern Ireland) 2016”.

Article 30(8) (evidence of certificates given by a food analyst or examiner)

For “this Order” substitute “the Food Safety (Information and Compositional Requirements) Regulations (Northern Ireland) 2016”.

Article 34 (obstruction etc. of officers)

In paragraph (1) for “this Order” (in each place occurring) substitute “the Food Safety (Information and Compositional Requirements) Regulations (Northern Ireland) 2016”.

Article 36(1) and (2) (punishment of offences)

In paragraph (1), after “Article 34(1)” insert “, as applied and modified by regulation 5 and Part 2 of Schedule 1 to the Food Safety (Information and Compositional Requirements) Regulations (Northern Ireland) 2016”.

After subparagraph (1), insert—
“(1A) A person guilty of an offence under Article 9(2), as applied by regulation 5(1) and Part 1 of Schedule 1 to the Food Safety (Information and Compositional Requirements) Regulations (Northern Ireland) 2016” shall be liable, on summary conviction, to a fine not exceeding level 5 on the standard scale.”.

In paragraph (2) for “any other offence under this Order” substitute “an offence under Article 34, as applied by regulation 5 and Part 2 of Schedule 1 to the Food Safety (Information and Compositional Requirements) Regulations (Northern Ireland) 2016.”.
SCHEDULE 2

Improvement Notices -specified provisions

PART 1

Requirements of the EU Regulation

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<th>Column 2 Provisions to be read with the provision of the EU Regulation</th>
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<td>Article 4(1)</td>
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<td>Article 4(2) (requirement for relevant food to be pre-packed)</td>
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<td>Article 9(1) (requirement for relevant food to satisfy nutritional requirements)</td>
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<td>Article 9(2) (prohibition on substances in dangerous quantities)</td>
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<td>Article 9(3) (requirements relating to substances added to relevant food)</td>
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<td>Article 9(5) (information not to be misleading etc.)</td>
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<td>Article 10(1) (information not to discourage breast feeding)</td>
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<td>Article 10(2) (labelling restrictions on infant formula and follow on formula)</td>
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PART 2

Requirements of the Infant Formula and Follow-on Formula Delegated Regulation

In this Part, except where otherwise provided, a reference to an Article or Annex is a reference to an Article of or Annex to the Infant Formula and Follow-on Formula Delegated Regulation.

A reference to “FIC” is a reference to Regulation (EU) no. 1169/2011

<table>
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<tr>
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<th>Column 2 Provisions to be read with the provision of the Infant Formula and Follow-on Formula Delegated Regulation</th>
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<td>2(2)</td>
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PART 3

Requirements of the Food for Special Medical Purposes Delegated Regulation

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SCHEDULE 3
Regulation 6

Revocations

(a) The Medical Food Regulations (Northern Ireland) 2000(a);
(b) The Notification of Marketing of Food for Particular Nutritional Uses Regulations (Northern Ireland) 2007(b);
(c) The Food for Particular Nutritional Uses (Miscellaneous Amendments) Regulations (Northern Ireland) 2007(c);
(d) The Infant Formula and Follow-on Formula Regulations (Northern Ireland) 2007(d);
(e) The Food for Particular Nutritional Uses (Miscellaneous Amendments) Regulations (Northern Ireland) 2010(e); and
(f) The Infant Formula and Follow-on Formula (Amendment) Regulations (Northern Ireland) 2014(f).

(a) S.R. 2000 No. 187
(b) S.R. 2007 No. 60
(c) S.R. 2007 No. 408
(d) S.R. 2007 No. 506
(e) S.R. 2010 No. 33
(f) S.R. 2014 No. 11
SCHEDULE 5

Regulation 7

Amendments to the Tryptophan in Food Regulations (Northern Ireland) 2005

1. The Tryptophan in Food Regulations (Northern Ireland) 2005(a) are amended in accordance with paragraphs 2 and 3.

2. In Regulation 2(1)(interpretation)—


   (b) for the definition of “follow on formula” substitute “‘follow on formula” has the same meaning as in Article 2 of Regulation 953/2009”;

   (c) for the definition of “infant formula” substitute “‘infant formula” has the same meaning as in Article 2 of Regulation 953/2009”;

   (d) for the definition of “processed cereal-based foods” and “baby foods” substitute “‘processed cereal-based food” and “baby food” have the same meaning as in Article 2 of Regulation 953/2009”;

(a) S.R. 2006 No.440